Im age

1653



Patent Docket P1718R1C1

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of

Vishva Dixit et al.

Serial No.: 10/607,882

Filed: June 27, 2003

For:

METHODS FOR MAKING

RECOMBINANT PROTEINS USING

APOPTOSIS INHIBITORS

Group Art Unit: 1653

Examiner: to be assigned

Confirmation No: 7220

Customer No: 09157

CERTIFICATE OF EXPRESS MAILING

Express Mail Number: EV 351 928 906 US

I hereby certify that this correspondence is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 CFR 1.10 on the date indicated below and is addressed to "Commissioner for Patents, P.O. Box 1450, Alexandria Virginia 22313-1450".

October <u>3</u>, 2003

Diane L. Marschang

TRANSMITTAL LETTER

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

Transmitted herewith are the following documents:

- Information Disclosure Statement;
- 2. Form PTO-1449 with 1 Reference;
- Copy of European Search Report;
- 4. Return postcard.

In the event any additional fees are due in connection with the filing of these documents, the Commissioner is authorized to charge such fees to our Deposit Account No. 07-0630.

Respectfully submitted,

GENENTECH, INC.

Date: October 3, 2003

Diane L. Marschang

Reg. No. 35,600

Telephone No. (650) 225-5416

Diane L Marschal





IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of

Vishva Dixit et al.

Serial No.: 10/607,882

Filed: June 27, 2003

For: N

METHODS FOR MAKING

RECOMBINANT PROTEINS USING

APOPTOSIS INHIBITORS

Group Art Unit: 1653

Examiner: to be assigned

Confirmation No: 7220

CUSTOMER NO: 09157

CERTIFICATE OF EXPRESS MAILING

Express Mail Number: EV 351 928 906 US

I hereby certify that this correspondence is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 CFR 1.10 on the date indicated below and is addressed to "Commissioner for Patents, P.O. Box 1450,

Alexandria Virginia 22313-1450".

October $\frac{3}{2}$, 2003

Diane L. Marschang

INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

Applicants submit herewith patents, publications or other information (attached hereto and listed on the attached revised Form PTO-1449) of which they are aware, which they believe may be material to the examination of this application and in respect of which there may be a duty to disclose in accordance with 37 CFR §1.56.

This Information Disclosure Statement is filed in accordance with the provisions of:

[X] 37 CFR §1.97(b)

- within three months of the filing date of the application other than a continued prosecution application under 37 CFR § 1.53(d); or
- within three months of the date of entry of the national stage of a PCT application as set forth in 37 CFR§1.491, or
- before the mailing of the first Office action on the merits; or
- before the mailing of the first Office action after the filing of a request for a continued examination under 37 CFR §1.114.

[] 37 CFR §1.97(c)

• by the applicant after the period specified in 37 CFR §1.97(b), but prior to the mailing date of any of a final action under 37 CFR §1.113, or a notice of allowance under 37 CFR §1.311, or an action that otherwise closes prosecution in the application, and is accompanied by either the fee set forth in 37 CFR §1.17(p) or a statement as specified in 37 CFR §1.97(e), as checked below.

[] 37 CFR §1.97(d)

 after the period specified in CFR § 1.97(c), and is accompanied by the fee set forth in 37 CFR § 1.17(p) and a statement as specified in 37 CFR § 1.97(e), as checked below.

[If either of boxes 37 CFR § 1.97(c) or 37 CFR § 1.97(d) is checked above, the following statement under 37 CFR § 1.97(e) may need to be completed.]

- [] 37 CFR §1.97(e) Each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this information disclosure statement.
- 37 CFR §1.704(d) Each item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application and the communication was not received by any individual designated in §1.56(c) more than thirty days prior to the filing of this information disclosure statement. Therefore, in accordance with the provisions of 37 CFR §1.704(d), the filing of this information disclosure statement will not be considered a failure to engage in reasonable efforts to conclude prosecution under 37 CFR §1.704.
- [] The U.S. Patent and Trademark Office is hereby authorized to charge Deposit Account No. 07-0630 in the amount of \$180.00 to cover the cost of this Information Disclosure Statement under 37 CFR §1.17(p). Any deficiency or overpayment should be charged or credited to this deposit account.

A list of the patent(s) or publication(s) is set forth on the attached revised Form PTO-1,449 (Modified). A copy of the European Search Report is attached.

A copy of reference number 30 is attached.

Those patent(s) or publication(s) which are marked with an asterisk (*) in the attached PTO-1449 form are not supplied because they were previously cited by or submitted to the Office in a prior application Serial No. 09/668,924, filed September 25, 2000 and relied upon in this application for an earlier filing date under 35 USC § 120.

Serial No.: 10/607,882 Filed: June 27, 2003

Page 3

A concise explanation of relevance of the items listed on PTO-1449 is:

[X] not given

[] given for each listed item

[] given for only non-English language listed item(s) [Required]

[] in the form of an English language copy of a Search Report from a foreign patent office, issued in a counterpart application, which refers to the relevant portions of the references.

In accordance with 37 CFR § 1.97(g), the filing of this information disclosure statement shall not be construed as a representation that a search has been made.

In accordance with 37 CFR § 1.97(h), the filing of this information disclosure statement shall not be construed to be an admission that the information cited in the statement is, or is considered to be, material to patentability as defined in 37 CFR § 1.56(b).

The Commissioner is hereby authorized to charge any additional fees required under 37 CFR 1.16 and 1.17 for this Information Disclosure Statement, or credit overpayment to Deposit Account No. 07-0630. A duplicate copy of this sheet is enclosed.

Respectfully submitted,

GENENTECH, INC.

Date: October <u>9</u>, 2003

Diane L. Marschang

Reg. No. 35,600

Telephone No. (650) 225-5416

By: Diane & Maische

#142261

FORM PTO-1449

6	PEVO
1	0 3 2003 E
PATENTS	RADEMARK

LIST OF DISCLOSURES CITED BY APPLICANT

U.S. Dept. of Commerce Patent and Trademark Office

Serial No. Atty Docket No. 10/607,882 P1718R1C1 **Applicant** Vishva Dixit et al Filing Date Group 1653 27 Jun 2003

(Use several sheets if necessary)

					27 Juli 200	1000	,	
			-	U.S. PATENT DOCUMENTS	,		-	<u> </u>
xaminer nitials		Document Number	Date	Name	Class	Subclass	Filing	Date
	* 1	6,072,047	06.06.00	Rauch et al.				
				FOREIGN PATENT DOCUMENTS	3			
Examiner						Transla		
nitials		Document Number	Date	Country	Class	Subclass	Yes	No
	* 2	WO 01/18185	15.03.01	PCT				
	* 3	WO 93/16192	19.08.93	PCT				
	* 4	WO 97/44443	27.11.97	PCT				
	* 5	WO 97/44444	27.11.97	PCT				
	* 6	WO 98/10778	19.03.98	PCT				
	* 7	WO 98/35986	20.08.98	PCT				
			OTHER DISCI	OSURES (Including Author, Title, Date,	Pertinent Pages, e	tc.)		
		Al-Rubeai and Sir	ngh, "Apoptosis	s in cell culture" Curr. Opin. Bi	otech. 9:152-15	6 (1998)		<u> </u>
	* 8							
<i>.</i>		Ashkenazi and Dix	cit., "Death Re	eceptors: Signaling and Modulation	n." <u>Science.</u> 28	1(5381):1305	5-1308 (1998)
	* 9	Marie Care						
			P NF-κB and IκE	Proteins: New Discoveries and In	nsights" <u>Ann. R</u>	ev. Immunol.	_ 14:649	-683
	*10	(1996)						
		Barr and Tomei,	'Apoptosis and	Its Role in Human Disease" Bio/T	echnology 12:48	7-493 (1994)		
*11								
	*12	Beidler et al., "The Baculovirus p35 Protein Inhibits Fas- and Tumor Necrosis Factor-induced Apoptos: Journal of Biological Chemistry 270:16526-16528 (1995)					tosis"	
Boldin et al., "Involvement of MACH, a Novel MORT1/FADD-Interacting Protease, in Fasters Receptor-Induced Cell Death" Cell 85:803-815 (1996)				in Fas/APO-1	l- and T	NF		
		Boldin et al., "Self-Association of the "Death Domains" of the p55 Tumor Necrosis Factor (TNF) Receptor						
	*14	1 1 5 mm 1 m 1 m 2 m 1 m 1 m 1 m 1 m 1 m 1 m						
	+15	Chinnaiyan and Di	ixit, "The Cell	l-Death Machine" <u>Current Biology</u>	6:555-562 (1996)		
	*15							
	*16	Chinnaiyan et al., "FADD, a novel death domain-containing protein, interacts with the death domain of Fas and initiates apoptosis" Cell 81:505-512 (1995)						
	~10		100000000000000000000000000000000000000		(3.50.4)			
	Chinnaiyan et al., "FADD/MORT1 Is a Common Mediator of CD95 (Fas/APO-1) and Tumor Necros: *17 Receptor-induced Apoptosis" Journal of Biological Chemistry 271:4961-4965 (1996)						Factor	
							Coll Dos	+ h #
	*18	Clem et al., "Prevention of Apoptosis by Baculovirus Gene During Infection of Insect Cells" <u>Science</u>					CII	
	*19						<u>ce</u>	
		Cleveland and Ih	le, "Contender:	s in FasL/TNF Death Signaling" <u>Ce</u>	<u>11</u> 81:479-482 (1995)		
	*20							
Examine	l	1			ate Considered	-		

*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

FORM PTO-1449

OLD 0.3 2003 STADEMARK GET

U.S. Dept. of Commerce
Patent and Trademark Office

Atty Docket No.
P1718R1C1

Applicant
Vishva Dixit et al

Filing Date

27 Jun 2003

Serial No.
10/607,882

Group
1653

LIST OF DISCLOSURES CITED BY APPLICANT

(Use several sheets if necessary)

(Use sev	veral sheets if necessary)	Filing Date 27 Jun 2003	1653		
	OTHER DISCLOSURES (Including Author, Title, Date,				
			BO4 AN 1997-380167		
*21	Database WPI <u>Section Ch. Week 199735</u> , <u>Derwent Publications Ltd., London, GB; Class B04, AN 1997-380167</u> (June 24, 1997)				
*22	Dickson, A. J., "Apoptosis regulation and its applications to biotechnology" TIBTECH 16:339-342 (1998)				
*23	Duan et al., "ICE-LAP6, a Novel Member of the ICE-Ced-3 Gene Family, Is Activated by the Cytotoxic T Cell Protease Granzyme B" <u>Journal of Biological Chemistry</u> 271(28):16720-16724 (1996)				
*24	Enari et al., "Involvement of an ICE-like protease in Fas-mediated Apoptosis" Nature 375:78-81 (1995)				
*25	Franek and Chladkova-Sramkova, "Apoptosis and nutrition: Involvement of amino acid transport system in repression of hybridoma cell death" Cytotechnology 18:113-117 (1995)				
*26	Fraser and Evan, "A License to Kill" <u>Cell</u> 85:781-784 (1996)				
*27	Fujita et al., "Overexpression of bcl-2 Improved Survival of COS-1 Cells and Enhanced Transient Protein Production" <u>Journal of Fermentation and Bioengineering</u> 82(6):589-591 (1996)				
*28	Fujita et al., "Reinforcing apoptosis-resistance of COS and myeloma cells by transfecting with bcl-2 gene" Cytotechnology 25:25-33 (February 1997)				
*29	Goswami et al., "Apoptosis in Batch Cultures of Chinese Hamster Ovary Cells" <u>Biotechnol</u> . <u>Bioeng</u> . 62:632-640 (1999)				
30	HG. Wang et al., "R-Ras Promotes Apoptosis Caused by Growth Factor Deprivation Via a Bcl-2 Suppressible Mechanism" The Journal of Cell Biology 129(4):1103-1114 (May 1995)				
*31	Hedge et al., "Blk, a BH3-containing Mouse Protein That Interacts with Bcl-2 and Bcl-xL, Is a Potent Death Agonist" The Journal of Biological Chemistry 273(14):7783-7786 (April 3, 1998)				
*32	Hsu et al., "TRADD-TRAF2 and TRADD-FADD interactions define two distinct TNF receptor 1 signal transduction pathways" Cell 84:299-308 (1996)				
*33	Itoh et al., "Overexpression of bcl-2, Apoptosis Suppressing Gene: Prolonged Viable Culture Period of Hybridoma and Enhanced Antibody Production" <u>Biotechnol</u> . Bioeng. 48:118-122 (1995)				
*34	Itoh et al., "The Polypeptide Encoded by the cDNA for Human Cell Surface Antigen Fas Can Mediate Apoptosis." Cell. 66:233-243 (1991)				
*35	Li et al., "Cytochrome c and dATP-Dependent Formation of Apaf-1/Caspase-9 Complex Initiates an Apoptotic Protease Cascade" Cell 91:479-489 (November 14, 1997)				
*36	Mastrangelo and Betenbaugh, "Overcoming apoptosis: new methods for improving protein-expression systems' TIBTECH 16:88-95 (1998)				
*37	Bioengineering 63(5):529-543 (June 5, 1999)				
*38	Mercille and Massie, "Induction of Apoptosis in Nutrient-Deprived Cultures of Hybridoma and Myeloma Cells" <u>Biotechnol</u> . Bioeng. 44:1140-1154 (1994)				
*39	Mercille et al., "Dose-Dependent Reduction of Apoptosis in Nutrient-Limited Cultures of NS/O Myeloma Cells Transfected with the E1B-19K Adenoviral Gene" <u>Biotechnology and Bioengineering</u> 63(5):516-528 ([A 1999)				
*40	Murray et al., "NSO Myeloma Cell Death: Influence of bcl-2 Overexpression" <u>Biotech. Bioeng.</u> 51(3):298-304 (1996)				
aminer	Da	te Considered			

*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

OCT 0 3 2003 FORM PTO-1449 LIST OF DISCLOSURES C

U.S. Dept. of Commerce Patent and Trademark Office

Serial No. Atty Docket No. P1718R1C1 10/607,882 **Applicant** Vishva Dixit et al Filing Date Group

(Use several sheets if necessary)

	OTHER DISCLOSURES (Including Auth			
*41	Muzio et al., "FLICE, A Novel FADD-Homologous ICE/C (Fas/APO-1) Death-Inducing Signaling Complex" Cell		ed to the CD95	
*42	Nagata, S., "Apoptosis by Death Factor." Cell. 88:355-365 (Feb 1997)			
*43	Pan et al., "Caspase-9, Bcl-XL, and Apaf-1 Form a Ternary Complex" <u>Journal of Biological Chemistry</u> 273(10):5841-5845 (1998)			
*44	Perkins et al., "Overexpression of Apaf-1 Promotes Apoptosis of Untreated and Paclitaxel- or Etoposide-treated HL-60 Cells" <u>Cancer Research</u> 58:4561-4566 (October 15, 1998)			
*45	pFLAG-CMV-2 Expression Vector, SIGMA PRODUCT INFORMATION			
*46	Presta et al., "Humanization of an Antibody Directed Against IgE" <u>J. Immunol.</u> 151(5):2623-2632 (September 1, 1993)			
*47	Ray et al., "Viral Inhibition of Inflammation: Cowpox Virus Encodes an Inhibitor of the Interleukin-1β Converting Enzyme" Cell 69:597-604 (May 15, 1992)			
*48	Seol and Billiar, "A Caspase-9 Variant Missing the Catalytic Site Is an Endogenous Inhibitor of Apoptosis" The Journal of Biological Chemistry 274(4):2072-2076 (January 22, 1999)			
*49	Shak et al., "Recombinant Human DNase I Reduces the Viscosity of Cystic Fibrosis Sputum" Proc. Natl. Acad. Sci. USA 87(23):9188-9192 (Dec 1990)			
*50	Simpson et al., "Prevention of Hybridoma Cell Death by bc1-2 During Suboptimal Culture Conditions" Biotechnol. Bioeng. 54:1-16 (1997)			
*51	Singh et al., "Cell Death in Bioreactors: A Role for Apoptosis" Biotechnol. Bioeng. 44:720-726 (1994)			
*52	Singh et al., "Enhancement of Survivability of Mammalian Cells by Overexpression of the Apoptosis-Suppressor Gene bcl-2" <u>Biotechnol</u> . Bioeng. 52:166-175 (1996)			
*53	Soo et al., "Overexpression of bcl-2 inhibits the apoptosis in rCHO" ABSTRACTS OF PAPERS AMERICAN CHEMICAL SOCIETY. 219TH MEETING OF THE AMERICAN CHEMICAL SOCIETY, SAN FRANCISCO, 26-30 MARCH 2000			
*54	219(1-2) (Abstract BIOT 245) Steller, H., "Mechanisms and Genes of Cellular Suicide" <u>Science</u> 267:1445-1449 (1995)			
*55	Suzuki et al., "Establishing apoptosis resistant cell lines for improving protein productivity of cell culture" Cytotechnology 23:55-59 (1997)			
*56	Tartaglia et al., "A novel domain within the 55 kd TNF receptor signals cell death" Cell 74(5):845-853 (1993)			
*57	Terada et al., "Improvement of Mammalian Cell Survival by Apoptosis-Inhibiting Genes and Caspase Inhibitors for Effective Use of Mammalian Cells" <u>Seibutsu-Kogaku Kaishi</u> 77(1):2-11 (January 25, 1999)			
*58	Tewari and Dixit, "Fas- and Tumor Necrosis Factor-induced Apoptosis Is Inhibited by the Poxvirus crmA Gene Product" <u>Journal of Biological Chemistry</u> 270:3255-3260 (1995)			
*59	Tewari and Dixit, "Recent Advances in Tumor Necrosis Factor and CD40 Signaling" Curr. Op. Genet. Develop. 6:39-44 (1996)			
*60	Tewari et al., "Yama/CPP32\$, a Mammalian Homolog of the Death Substrate Poly(ADP-Ribose) Polymerase" Ce		Protease That Cleave	
niner		Date Considered		

FORM PTO-1449

LIST OF DISCLOSURES CITED BY APPLICANT

U.S. Dept. of Commerce
Patent and Trademark Office

Atty Docket No.
P1718R1C1 10/607,882

Applicant
Vishva Dixit et al

Filing Date Group
27 Jun 2003 1653

(٤	Jse sev	reral sheets if necessary)	Filing Date 27 Jun 2003	Group 1653
		OTHER DISCLOSURES (Including Author, Title, Date,	Pertinent Pages, etc.)	<u> </u>
···-	*61	tSANG, "Mammalian Expression Vector with Two Multiple Cloning St Biotechniques 22(1):68 (1997)	ites for Expression o	f Two Foreign Genes"
-	*62	van de Goor et al., "Inhibition of Apoptosis in Biofactors by "A Meeting on Programmed Cell Death (abstract only) pps. 228 (1999)		" Cold Spring Harbor
	*63	Verma et al., "Rel/NF-KB/IKB Family: Intimate Tales of Associati 9:2723-2735 (1995)	on and Dissociation"	Genes Develop.
	*64	Zanghi et al., "Serum Protects Protein-Free Competent Chinese Ha Induced by Nutrient Deprivation in Batch Culture" <u>Biotech</u> . <u>Bioer</u>		ainst Apoptosis
	*65	Zhou et al., "Fed-Batch Culture of Recombinant NSO Myeloma Cells Production" <u>Biotechnology and Bioengineering</u> 55(5):783-792 (Sept		l Antibody
	*66	Zou et al., "Apaf-1, a Human Protein Homologous to C. elegans CE c-Dependent Activation of Caspase-3" Cell 90:405-413 (1997)	ED-4, Participates in	Cytochrome
			*	
			· ,, · · · · · · · · · · · · · · · · ·	
Examine	er	Da	te Considered	
*Examir	ner: In in con	itial if reference considered, whether or not citation is in conformance with MPEP of formance and not considered. Include copy of this form with next communication to	609; draw line through citato applicant.	ion